TAMOXIFEN
A Major Medical Mistake?

Once praised for its benefits in preventing breast cancer recurrence, the lucrative pharmaceutical drug tamoxifen is now implicated in causing dangerous side-effects including other types of cancers.

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In the early 1970s, a shameful chapter closed on the widespread use of a known carcinogenic and endocrine-disrupting drug called DES (diethylstilboestrol), the first synthetic, non-steroidal oestrogen drug. Against the advice of its creator, Sir Charles Dodd, between four and six million American and European women and 10,000 Australian women innocently used DES for the prevention of miscarriage and pregnancy complications.

In addition, DES became a popular though unproven drug for a variety of other conditions. It was used for the suppression of lactation, the treatment of acne, the treatment of certain types of breast and prostatic cancer, and as an inhibitor of growth in young girls, an oestrogen replacement in menopause and a "morning after" pill.

It would take 30 years to accept what laboratory tests had indicated as early as 1938—that DES was a highly dangerous and harmful drug. It was reported that, 20 years after taking DES, mothers had a 40 to 50 per cent greater risk of breast cancer than non-exposed mothers. In addition, the children of DES mothers showed a high incidence of reproductive abnormalities, miscarriages, vaginal cancer, testicular cancer, sterility and immune dysfunction. In fact, it is feared that repercussions of this drug will be felt for generations to come.

The irony of this entire debacle is that the medical establishment finally acknowledged that DES was useless in preventing miscarriages. Thus, DES, another disastrous experiment on women, was added to the long list of major medical blunders.

Out of this early research, a new drug appeared on the horizon which would be soon be heralded as a shining star in the war against the growing epidemic of breast cancer. In the late 1960s the pharmaceutical industry developed a drug called "tamoxifen". As a synthetic, non-steroidal compound with hormone-like effects (many of which are poorly understood), tamoxifen has a similar structure to DES. In fact, it was observed that tamoxifen caused the same abnormal changes seen in cells of women taking oestradiol and DES.[1] This similarity raised alarm bells for some.

Pierre Blais, well known as a drug researcher who was ejected from Canada's health protection bureaucracy when he spoke out about silicone breast implants, describes the story of tamoxifen as "the story of modern drug design which produces garbage drugs". He says, "Good drug design ceased, unfortunately, in the 1930s." Tamoxifen, Blais asserts, "...is a garbage drug that made it to the top of the scrap heap. It is a DES in the making."[2]

Blais's dire predictions were ignored with the promise of a potential drug treatment for breast cancer. Tamoxifen was first approved by the US Food and Drug Administration (FDA) for use as a birth-control pill; however, it proved to induce rather than inhibit ovulation. Although tamoxifen didn't work as a contraceptive, it was found to lower mammary cancer rates in animals. Animal studies showed that tamoxifen prevented oestrogen from binding to receptor sites on breast tissue cells. Tamoxifen also reduced the incidence of breast cancer in rodents after administration of a breast-carcinogenic substance. This discovery provided the impetus to study its effects in treating human breast cancer.

Oestrogen is the common link between most breast cancer risk factors, i.e., genetic, reproductive, dietary, lifestyle and environmental. It both stimulates the division of breast cells (healthy as well as cancerous) and, especially in its 'bad' form, increases the risk of breast cancer. Thus, hormonal drugs such as tamoxifen that block the effects of oestrogen on the breast were expected to reduce the risk of breast cancer recurring in women treated for breast cancer.[3]

Tamoxifen acts as a weak oestrogen by competing for oestrogen receptors much as

phyto-oestrogens do. Like phyto-oestrogens, tamoxifen has mild oestrogenic properties but is considered an anti-oestrogen since it inhibits the activity of regular oestrogens. More accurately, tamoxifen is an oestrogen-blocker. It fights breast cancer by competing with oestrogen for space on oestrogen receptors in the tumour tissue. Every tamoxifen molecule that hooks onto an oestrogen receptor prevents an oestrogen molecule from linking up at the same site. Without a steady supply of oestrogen, cells in an oestrogen-receptor-positive (ER+) tumour do not thrive and the tumour's ability to spread is reduced.[4]

However, tamoxifen exhibited two conflicting characteristics. It could act either as an anti-oestrogen or as an oestrogen. Therefore, while tamoxifen is anti-oestrogenic to the breast, it also acts as an oestrogen to the uterus and, to a lesser extent, the heart, blood vessels and bone. So, although it initially showed the tendency to counter breast cancer recurrence, it would soon be revealed that it also promoted particularly aggressive uterine and liver cancers, caused fatal blood clots and interfered with many other functions.

Doctors, however, were quick to jump on the tamoxifen bandwagon, turning a blind eye to its more injurious tendencies. Starting in the 1970s oncologists began using tamoxifen to treat women with cancer, often in combination with other drugs, radiation or surgery such as lumpectomy and mastectomy, with modest success. Like DES, tamoxifen's benefits were then extended for use as a preventive against osteoporosis and heart disease.

Today, doctors are treating about one million American breast cancer patients with tamoxifen, about 20 per cent of them for more than five years. As studies published in the *New England Journal of Medicine* in 1989 and the *Journal of the National Cancer Institute* in 1992 showed, women with breast cancer who took tamoxifen reduced their chances of developing cancer in the other breast (counterlateral cancer) by about 30 to 50 per cent.[5] These findings would later be challenged.

Tamoxifen is now recommended for all premenopausal women with hormone-positive cancers, as well as for most postmenopausal women with breast cancer and/or a growing number of women with hormone-negative cancers. Tamoxifen is currently used by more women with breast cancer than any other drug.[6]

Tamoxifen (brand name Nolvadex) is now the most widely prescribed cancer medication in the world. It generated revenues of US$265 million in 1992. By 1995, worldwide sales of Nolvadex reached $400 million.[7] And at AUD$90 for one month's supply, it doesn't come cheap (the Australian Pharmaceutical Benefits Scheme covers $70).

Tamoxifen was developed by UK-based Imperial Chemical Industries (ICI), one of the world's largest multinational chemical corporations. Zeneca, an ICI subsidiary, is responsible for manufacturing and marketing the hormone and is now the world's largest cancer-drug company.

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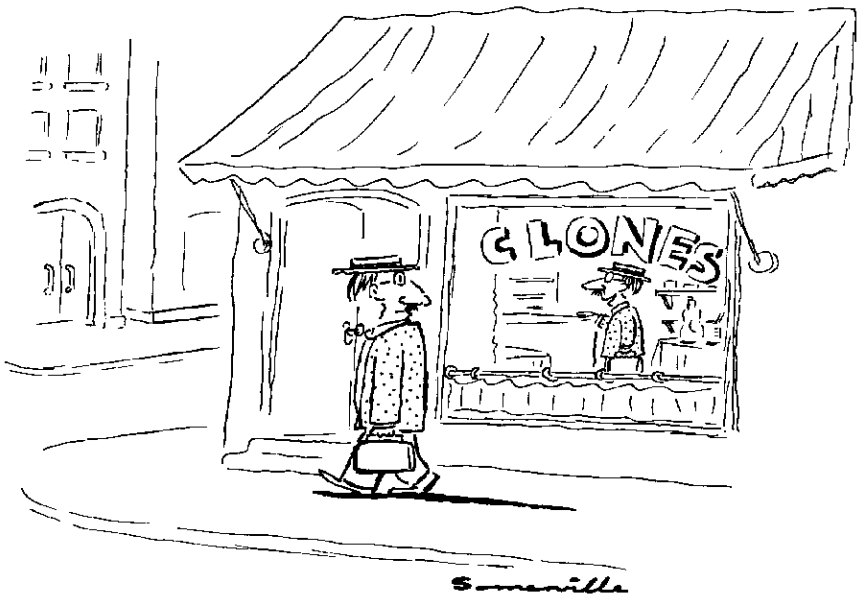
It is no surprise that ICI's profits come from playing both sides of the cancer industry. ICI's agrochemical division, which includes Zeneca, manufactures chlorinated and other industrial chemicals including herbicides. All are poisonous, and many are known endocrine-disruptors that have been incriminated as causes of breast cancer. ICI's profits swell by manufacturing chemicals that on the one hand *cause* breast cancer, and on the other hand reputedly *cure* breast cancer.

LIMITED BENEFITS OF TAMOXIFEN

Tamoxifen 's benefits are determined by several factors:[8]

- Postmenopausal women who are ER-positive (have a positive oestrogen receptor status) get the most benefit.
- For postmenopausal women who are ER-negative, the benefits appear to outweigh the risks.
- For premenopausal women who are ER-positive, it's a tough call. Potential benefits are small.
- Premenopausal women who are ER-negative receive virtually no benefit.
- Tamoxifen is more effective in women who have cancer in their lymph nodes than in those whose nodes are cancer-free.



In 1992 the *Lancet* published a review of a number of studies in which a total of 30,000 breast cancer patients were randomly assigned either to take tamoxifen or not. The average patient in this collaborative study was followed up for between five and six years. Of the patients taking tamoxifen, 74.4 per cent survived, as compared with 70.9 per cent in the non-tamoxifen group—a less-than-impressive improvement.

The report found that the group helped most consisted of postmenopausal women with ER-positive status. The study went on to report that premenopausal women who are ER-negative had absolutely no benefit from taking tamoxifen.[9]

Despite tamoxifen's proven ability to reduce breast cancer recurrence in postmenopausal women, major studies have shown that tamoxifen reduces death from breast cancer only marginally.[10] The majority of women who take tamoxifen live no longer than women who do not take it.[11] Furthermore, some breast cancers learn how to use tamoxifen to stimulate their growth.

The benefits of tamoxifen are limited. Virtually all women who take it become resistant within five years.[12] A recent randomised, controlled study showed that tamoxifen reached its maximum protective effect on breast tissue with women who took it for five years. Taking it for five more years didn't offer any more protection, and may actually have caused more cancers. In other words, after a while the breast cells become resistant to tamoxifen and actually start to be fed by it.[13]

This result surprised the researchers. According to Dr Susan Love, author of *Dr Susan Love's Hormone Book*: "This is a dramatic example of why you need good, long-term studies. If we had based all of our recommendations on the five-year data without doing further studies, we would have had women taking tamoxifen forever. So convinced were we that tamoxifen was a wonder drug that the only reason researchers did the later study at all was to prove it wrong. Luckily, we found out that we were wrong in time to prevent doing further damage. We have learned, not for the first time, that more isn't always better."[14]

TAMOXIFEN'S DARK SIDE

While the initial findings of tamoxifen's role in breast cancer treatment seemed so promising, as with so many of the synthetic hormone drugs, further research presented grave concerns for its widespread use. In fact, the *MIMS Annual* lists 25 adverse reactions to tamoxifen; some of these can be fatal.

Menopausal Symptoms

Tamoxifen often induces menopausal symptoms in menstruating women. About half of these women experience hot flushes. Fluid retention and weight gain occur in about 25 per cent of women and can be controlled by reducing the dose. Vaginal discharge and vaginal atrophy are additional symptoms. Some studies have also found that premenopausal users are at risk of developing accelerated bone-mineral loss and osteoporosis.

Menstrual irregularities also occur in premenopausal women. Amenorrhoea (absence of the menstrual cycle) often results and can be permanent.

Eye Damage

According to a 1978 study in *Cancer Treatment Reports* and another published in *Cancer* in 1992, about six per cent of women taking even low-dose tamoxifen suffer damage to the retina and corneal opacities and decreased visual acuity. Irreversible corneal and retinal changes can occur in those taking 20 mg of tamoxifen twice a day (twice the usual dose). These changes may have no immediate effect on visual acuity, but may predispose the eyes to later problems including cataracts.

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In May 1995, the state's Carcinogen Identification Committee voted unanimously to add tamoxifen to its list.

Blood Clots

Tamoxifen irritates the walls of the veins, and inflammation (a natural healing response to irritation) follows. The constant irritation and inflammation weakens the veins, causing bleeding, clotting, thrombophlebitis and, in the worst cases, obstruction of the blood vessels serving the lungs, which can be deadly and can occur with little warning. The incidence of thrombophlebitis in women using oral contraceptives is generally regarded as significant (1 in 2,000); however, with tamoxifen it's 30 times greater.[15]

Several studies, including one reported to the FDA's Oncological Drugs Advisory Committee by the National Surgical Adjuvant Breast and Bowel Project in 1991, showed that the risk of developing life-threatening blood clots increases about seven times in women taking tamoxifen.[16]

Psychological Symptoms

Depression has been reported as a potential side-effect of tamoxifen in 30 per cent of women. Cases have been reported of an inability to concentrate.

It is important that patients observe their moods and mental states. If it is suspected that tamoxifen is causing depression or lack of concentration, it is suggested that a period of tamoxifen avoidance be considered.

Other Symptoms

Tamoxifen can trigger asthma attacks in some sensitive patients.

Changes to the vocal cords resulting in impairment of singing and speaking abilities are occasionally caused by tamoxifen.

CARCINOGENENIC EFFECTS

It wasn't long before laboratory studies showed that tamoxifen acted as a carcinogen. It has been found that tamoxifen binds tightly and irreversibly to DNA, the genetic blueprint of a cell, causing a cancerous mutation to take place. Even Australia's conservative National Health and Medical Research Council (NHMRC) warned that no amount of tamoxifen is safe when it comes to carcinogenic effects.

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Following suit, in 1996 the World Health Organization formally designated tamoxifen a human carcinogen, grouping it with 70 other chemicals—about one quarter of them pharmaceuticals—that have received this dubious distinction.

Liver Cancer and Liver Disease

Tamoxifen is toxic to the liver, and there have been reports of acute hepatitis in patients treated with tamoxifen. Liver damage has occurred in every animal given tamoxifen. According to Gary Williams, medical director of the American Heart Foundation, tamoxifen has been shown in animal studies to be a "rip-roaring" liver carcinogen, inducing highly aggressive cancers in about 12 per cent of rats.[17]

The latest human studies show a sixfold increase in liver cancer among women taking tamoxifen for more than two years.[18] Liver failure and tamoxifen-induced hepatitis, although rare, have been reported. Even Zeneca admits that tamoxifen is a liver carcinogen—while nevertheless aggressively promoting its use.

Uterine (Endometrial) Cancer

As early as 1967, ICI scientists noted that "tamoxifen persists for some days in the uterus". In rats, a tamoxifen metabolite (a breakdown compound almost similar in structure to the original) was found to influence the uterus to be more receptive to oestrogen. (The more oestrogen, the greater the chance of unnatural cell-division leading to cancer.) ICI also reported liver carcinogenicity of tamoxifen as well as both ovarian and testicular tumours in mice in its description of the drug in the standard *Physicians Desk Reference*.

Uterine growths such as polyps, tumours, endometrial thickenings and cancers occur in a significant number of women taking tamoxifen. One study detected abnormal endometrial cells in subjects the day after the first tablet was taken.[19] Precancerous uterine and endometrial changes were seen in 10 per cent of the women taking tamoxifen in a recent study. The higher the dose of tamoxifen and the longer it is taken, the greater the risk of changes. Women taking the standard dose of 20 mg for two years run a risk of uterine cancer that is 2 to 3 times greater than normal. After five years, the risk is 6 to 8 times greater.[20]

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In February 1996 a review by the International Agency for Research on Cancer, composed of scientists from various countries, definitively concluded that "there is sufficient evidence to regard tamoxifen as a human carcinogen that increases a woman's risk of developing cancer of the endometrium, the inner lining of the uterus".[21]

A large Swedish study linking tamoxifen to uterine cancer forced Zeneca to send letters in April 1994 to 380,000 physicians across the USA, in defence of the drug. The Swedish researchers had studied 1,371 breast cancer patients who took 40 mg per day for two to five years and found that there was a sixfold increase in uterine cancer among those patients who took tamoxifen when compared to 1,327 who did not. A second study involving patients who took 20 mg per day (the recommended dose) also showed a marked increase in uterine cancers compared with the control group.[22]

When the news came out that breast cancer patients who took tamoxifen for five years or longer (the same regimen that seems to prevent recurrence) might have tripled their risk of uterine cancer, British cancer researcher Richard Peto, head of the cancer research unit at Oxford University, sought to dismiss it. If caught early, he said, endometrial cancer seldom kills, so "it's no big deal". That statement infuriated critics who noted that the treatment for uterine cancer is hysterectomy. Dr Adriane Fugh-Berman, a leading women's health activist, angrily responded: "To some of us, it *is* a big deal to lose your uterus."

Shortly after Peto's flip dismissal of uterine cancers, researchers at the M. D. Anderson Cancer Center at Houston and at Yale University School of Medicine discovered that breast cancer patients who develop uterine cancer while using tamoxifen are likely to have a fast-moving, lethal form of the disease.[23]

It should be noted that tamoxifen has also been associated with gastrointestinal cancers.

Breast Cancer

The premise for taking tamoxifen is its supposed role in protecting breast cancer patients from recurrence of the cancer. It was further postulated that it prevented breast cancer from occurring in the opposite breast (contralateral).

However, disturbing findings continue to surface, challenging tamoxifen's effectiveness. In 1992 the *New England Journal of Medicine* showed that tamoxifen may reduce the incidence of contralateral cancer, but this was demonstrated only in premenopausal women and only in three out of eight trials. In another 1992 study, reported in *Octa Oncologica*, it was shown that tamoxifen not only failed to reduce contralateral cancers in premenopausal women, but it actually increased their incidence.[24]

The irony of tamoxifen is that, while widely publicised as the leading treatment against the recurrence of breast cancer, it is a known and listed carcinogenic substance.

Heart Disease and Osteoporosis

Another promise of tamoxifen was its supposed protective benefits for the heart and bones. It was theorised that its oestrogenic properties would help reduce heart disease and osteoporosis in women, but once again the theory crumbled under the weight of hard facts.

Several trials with tamoxifen failed to show that it has any effect on bone density and thus on prevention of osteoporosis. In three other trials, bone density increased slightly in lower spinal vertebrae but not in longer bones or hip bones which are particularly susceptible to fractures and potentially fatal complications.

Initial data seemed to indicate that it decreased the incidence of heart attacks, but they have been disproved by more recent studies. According to Dr Susan Love: "It doesn't seem to have a bad effect on lipids, but that's a far cry from preventing heart attacks."

A detailed review of the drug's alleged protective cardiovascular effects prompted the British National Heart, Lung and Blood Institute, a once strong proponent of tamoxifen, to withdraw its support because the evidence of benefit proved so inadequate.[25]

According to the January 1996 issue of *The Network News*, it was reported at a closed-door meeting of the National Cancer Institute that tamoxifen failed to prevent heart disease in breast cancer patients.

THE BREAST CANCER PREVENTION TRIAL

Based far more on wishful thinking than on science, the US National Cancer Institute (NCI) leaped to the conclusion that tamoxifen's anti-oestrogenic effects in relation to breast cancer

treatment meant that the drug would prevent breast cancer from developing in healthy women.

Disregarding all the research implicating tamoxifen with serious and potentially fatal side-effects, the NCI launched a US$60 million breast cancer prevention trial in April 1992, aiming to recruit 16,000 healthy women in the United States, Europe, Canada, Australia and New Zealand. Still ongoing, the trial now involves 13,000 healthy women over the age of 35 who are considered at high risk. Australia has recruited 1,350 women, with a target of 2,500. For five years, half the women receive tamoxifen and half receive a placebo. The drug is supplied free of charge by manufacturer Zeneca.

Dr Samuel Epstein, Professor of Occupational and Environmental Medicine at the University of Illinois School of Public Health and author of *The Breast Cancer Prevention Program*, raises serious concerns. "Unfortunately, this misguided and dangerous approach to prevention stems from the entrenched fixation of the NCI on the use of chemical drugs to prevent cancer which may have been induced by chemical pollutants, medical technology (such as radiation from X-rays) and carcinogenic/oestrogenic drugs in the first place. Instead of attempting to reduce the carcinogenic chemical burden under which we struggle to maintain our health, the NCI believes that the solution is to add more chemicals to the mix."

Once again, healthy women are targeted as the guinea pigs for a drug treatment that has already been proven to be a cause of a variety of cancers including breast cancer.

Dr Susan Love concurs: "It is a sad state of affairs when we have to add yet more chemicals to counteract the effects of other chemicals."

This attitude extends to the way the NCI treats the women in the trial. They are given no guidance on alternative protective measures such as increasing exercise, maintaining a healthy weight, eating a protective diet and avoiding exposure to environmental carcinogens; nor are they being fully informed about the serious risks of tamoxifen.

Dr Lynette Dumble, Senior Research Fellow in History and Philosophy of Science at the University of Melbourne, believes that the global trial to prevent breast cancer with tamoxifen is a modern and very large chapter of "medical imperialism". Back in October 1994 she commented on ABC TV's *Quantum* science program that the tamoxifen trial was the medical equivalent of mutilating surgery which prevents a woman from developing breast cancer by cutting off both her breasts.

Dr Dumble sees women as vulnerable guinea pigs for the trial, and questions both the breast cancer risk of healthy women volunteering for the trial (how can you tell whether fate or tamoxifen prevents a woman from developing breast cancer?) and the terms of the trial's positives and negatives (if a woman dies of tamoxifen-related endometrial or liver cancer, does this count as a tamoxifen success in preventing breast cancer?).

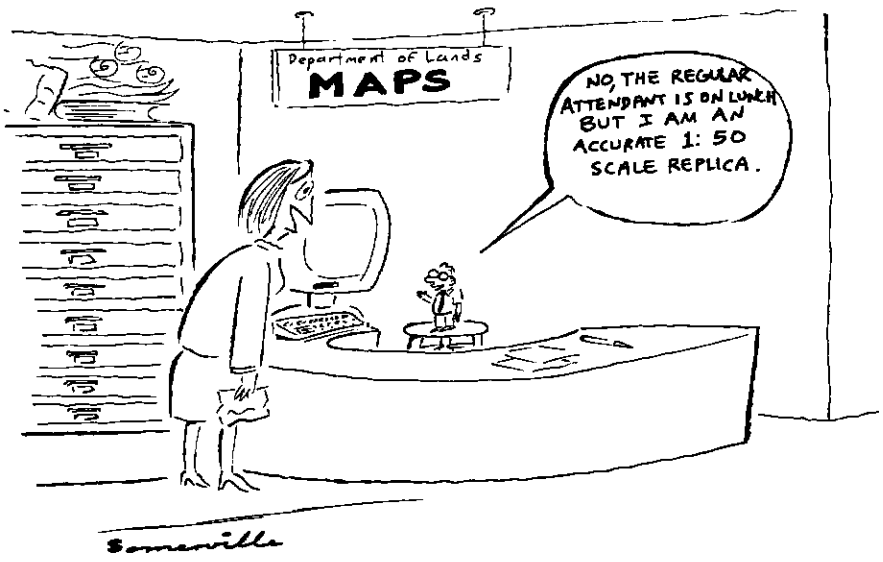
It seems absurd, but why would the powers-that-be continue to promote a trial that promises to substitute one cancer for another in otherwise healthy women? Once again, healthy women are targeted as the guinea pigs for a drug treatment that has already been proven to be a cause of a variety of cancers including breast cancer. In the case of tamoxifen, medical research has once again taken a back seat to profits. It is the population that is at risk. The cancer establishment would certainly be eager to prove a tamoxifen-prevention role, since it would then open up another huge, billion-dollar market.

ALTERNATIVES TO TAMOXIFEN

While the cancer establishment continues to invest vast amounts of money into research, manufacturing and trialling of harmful drugs for the prevention and hopeful cure of breast cancer, there are safer and more effective options that already exist.

Oestriol, one of the oestrogens produced by the ovaries, is considered a safe oestrogen in that it has been shown to inhibit breast cancer. Dr Henry Lemon and his colleagues conducted a study in women who already had breast cancer that had spread to other areas of the body. One group was given oestriol and another not. At the end of the study, 37 per cent of those women who received oestriol had either a remission or an arrest of their cancer.[26] Might not oestriol, a natural, safe hormone with almost no side-effects, be able to accomplish what tamoxifen does but without the toxic side-effects?

There is also convincing evidence that natural progesterone has an important role in breast cancer treatment and prevention. A study conducted in 1981 at Johns Hopkins University revealed that when a group with a low progesterone level was compared with a normal-level progesterone group, it was found that the occurrence of breast cancer was 5.4 times greater in the women in the low progesterone group. That is, the incidence of breast can-



cer in the low progesterone group was over 80 per cent greater than in the normal progesterone group. When the researchers looked at the low progesterone group for all types of cancer, they found that these women experienced a tenfold increase in all malignant cancers, compared to the normal group.

In a 1995 study published in the *Journal of Fertility and Sterility*, researchers found that women using a topical progesterone cream had dramatically reduced breast cell multiplication rates compared to women using either a placebo or oestrogen. This exciting study demonstrated that natural progesterone creams impressively decreased breast cell proliferation rates.[27]

Lifestyle factors also play a significant role. In a prospective study of 25,624 Norwegian women aged 20 to 54, after an average of 14 years of follow-up the investigators found strong evidence that everyday exercise, both at work and at leisure, reduced the breast cancer risk. Women who exercised at least four hours a week during leisure time were found to have a 37 per cent reduction in risk of breast cancer, compared with sedentary women. The study found that the more time spent exercising, the lower the breast cancer risk.[28]

As Dr John Lee pointed out in his best-selling book, *What Doctors May Not Tell You About Menopause*: "Herbs and food contain phyto-oestrogens. Their benefit parallels that of tamoxifen (without the adverse side-effects) in that phyto-oestrogens occupy oestrogen receptors and are less oestrogenic than those made by the body. Since it is now known that reducing caloric intake reduces oestrogen levels, and recent studies find 46 per cent less breast cancer among women consuming more fruit and vegetables, it would seem that women interested in preventing breast cancer could make modest changes in diet and derive better and certainly safer results."[29]

History continues to repeat itself. Time and time again women have been reassured that the wonder drugs or treatments offered them would be their salvation, only to discover they were exposed to harmful carcinogenic and mutagenic chemicals.

It is widely believed that today's drugs are tomorrow's poisons.

In the case of tamoxifen, tomorrow has already arrived.

In addition to the DES debacle, the disasters of thalidomide, silicone breast implants, oestrogen replacement therapy and now tamoxifen (to name just a few) continue to demonstrate how readily women's lives have been sacrificed in the pursuit of profits. The warnings have been drowned out by the glossy advertising campaigns and the reassurances of "medical experts".

There are solutions to the breast cancer epidemic. However, they will be found more by altering lifestyle, dietary and stress factors, and reducing or eliminating exposure to the many known toxic, carcinogenic chemicals that are polluting the environment, than by some miraculous drug discovery. It is also up to women not only to continue to become fully educated about safe health options but to demand them from health providers. Too many women have already been maimed and sacrificed to unproven and unsafe drug treatments.

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